REMARKS

A. Background

Claims 51-78 were pending in the application at the time of the Office Action with claims 61, 62 and 73 having been withdrawn. Claims 51-60, 63-72 and 74-78 were rejected as being obvious over cited art. By this response, applicant has amended independent claims 51 and 70 and added new dependent claims 79 and 80. As such, claims 51-60, 63-72, and 74-80 are presented for the Examiner's consideration in light of the following remarks.

B. Proposed Claim Amendments.

Applicant has herein amended claims 51 and 70 and added new claims 79 and 80 to further clarify, more clearly define, and/or broaden the claimed inventions to expedite receiving a notice of allowance. For example, independent claims 51 and 70 have been amended to clarify that the hydrogen peroxide/water vapor is caused to "simultaneously and continuously condense onto substantially all surfaces bounding or within the enclosed space." Applicant submits that the amendments to the claims are supported throughout the application, and at least at p. 6, lines 2-5; and p. 16, lines 22-26 In view of the foregoing discussion, applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejections Based on 35 USC § 103

1. Claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78

Paragraphs 2 and 3 of the Office Action reject claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78 under 35 USC § 103(a) as being unpatentable over WO 00/74734 to Watling ("*Watling*") in view of U.S. Patent No. 6,630,105 to O'Neill et al. ("*O'Neill*"). Specifically, the Office Action concedes that

that *Watling* "does not appear to disclose that the steps of creating a recirculating heated airstream and progressively introducing hydrogen peroxide/water vapour into the recirculating heated airstream are performed by an apparatus that is disposed within the enclosed space." Office Action at page 3. The Office Action then cites to *O'Neill* to remedy this shortcoming of *Watling*, asserting that "a claimed device that is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results (see MPEP 2144.04)." Office Action at page 4.

Applicant respectfully traverses this rejection and asserts that one of skill in the art would not simply move the *Watling* apparatus within the enclosure as alleged in the Office Action.

As discussed in prior responses, *Watling* discloses a fixed sterilizing apparatus used to repeatedly sterilize a sealed enclosure 1. For example, the sterilizing apparatus can be used to repeatedly sterilize an operating room which would correspond to sealed enclosure 1. The apparatus includes a preparation region (also called the "means of processing" or "processing means") located outside of sealed enclosure 1. The preparation region includes, among other things, a filter 4, a purifier 5, a heater 7, a fan or pump or compressor 8, a pressure controller 21, a flow measurement device 9, another filter 25 and an evaporation chamber 10, connected together via pipes or ductwork and controlled by a controller module 19.

During operation, as the gas circulates outside the enclosure, the gas is heated by heater 7 and the decontaminant gas (typically hydrogen peroxide) and water vapor mixture are dispensed into the gas in the evaporation chamber 10. See, e.g., *Watling* Abstract. The heated mixture is then passed back into the sealed chamber to form a condensate on the surfaces of the container. See p. 2, line 35 to p. 3, line 20; p. 6, lines 1-4. During this process, the *Watling* apparatus generates heat that is easily dissipated because the *Watling* apparatus is disposed outside of the sealed enclosure.

One of the objects of *Watling* is to provide improved sterilization by condensing a uniform "micro-condensation" layer of the decontaminant on all surfaces within sealed enclosure 1. See pages 5 and 7. This "micro-condensation" layer is achieved by increasing the concentration of the decontaminating gas within sealed enclosure 1 to a level above the dew point, monitoring the deposition of the "micro-condensation" layer, and then lowering the concentration of the decontaminating gas within sealed enclosure 1 to a level below the dew point. Controlling the dew point, and thus the deposition of the "micro-condensation" layer, is achieved by carefully controlling parameters such as pressure, temperature, and gas concentration within sealed enclosure 1. See p. 7, lines 21-33

As noted above, the Office Action alleges that it would have been obvious to simply make the entire Watling apparatus portable or movable so as to move the Watling apparatus within the sealed enclosure and thus read on the claimed invention. Applicant respectfully disagrees and submits that the *Watling* system would not function as intended if the system was simply made portable and moved within the sealed enclosure. As noted above, the *Watling* apparatus generates heat that is dissipated outside of the sealed enclosure. If the *Watling* apparatus was instead disposed entirely within the sealed enclosure, the heat generated by *Watling* would not be able to be dissipated outside the sealed enclosure, but would simply build up within the enclosure, causing the temperature to rise within the enclosure.

However, the central idea behind the process delivered by the device of *Watling* is the condensation of the vaporized sterilant on all surfaces within the enclosed space in which the sterilant is deployed. As discussed above, to control the deposition of the micro-condensation layer, parameters within enclosed space 1, such as pressure, temperature, and gas concentration, must be strictly controlled. In order to ensure a satisfactory deployment, it is imperative to ensure that the onset of

onset of condensation is detected. The onset of condensation is typically determined by continuously measuring the vapour concentration by a suitable instrument and identifying a peak and plateau of the vapour concentration over time. This only occurs if the temperature within the enclosed space is strictly controlled. Yet with the entire *Watling* apparatus disposed within the sealed enclosure, the temperature would rise and not be controlled.

As is known in the art, as the temperature increases in an enclosed space, the vapour pressure at which condensation occurs also increases. This would cause at least two problems with the *Watling* apparatus. First, the quantity of sterilant vapour required to saturate the gas would increase, thereby suppressing condensation on the surfaces. Second, even if, *arguendo*, some condensation was possible with the rising temperature, the changing vapour concentrations caused by the temperature increases would make it impossible to detect the identifying peak and plateau that indicate the occurrence of condensation. That is, because the saturation vapour pressure would be continuously changing, no clearly defined peaks or plateaus would be evident. This would effectively make the control or termination of the process problematic. In sum, placement of the *Watling* apparatus inside the enclosure where it is to be deployed for delivering sterilant vapour *only to the point of condensation* is likely to (a) inhibit the condensation process and (b) compromise the key process control indicator; for these reasons, *inter alia*, such an action would be *counterintuitive* to anyone ordinarily skilled in the art. As such, one skilled in art would not simply position the preparation region of *Watling* within sealed enclosure 1 because *Watling* would no longer function as intended.

Furthermore, moving the entire *Watling* device inside a sealed enclosure would cause other problems as well. A few examples include:

- If all of the controls were also located within the enclosure, this would be extremely dangerous; the environment inside the enclosure would be toxic to anybody monitoring and controlling the *Watling* device due to the high levels of concentration of the sterilant/gas mixture. If the controls were moved to the outside of the enclosure, vapour tight electrical connections from the inside to the outside of the sealed environment for the controls, the sensors etc. would need to be made. Not only would this require more work, it would also make the *Watling* device non-portable, countering the Examiner's reasoning.
- The *Watling* apparatus would need to be redesigned so as to be protected against the toxic and corrosive nature of the sterilant/gas mixture and condensate to which the apparatus would be constantly exposed.
- The *Watling* apparatus would need to be redesigned so as to guarantee that the *entire* apparatus was sterile after the apparatus is removed from the sealed enclosure to prevent cross-contamination during relocation.

In contrast, embodiments of the current invention have overcome the aforementioned issues using inventive components and methods, as set forth in the application.

In light of the foregoing discussion, Applicant respectfully submits that the Office Action has failed to establish a *prima facie* case of obviousness with respect to claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78 at least because the Office Action has failed to show that it would have been obvious to combine *Watling* and *O'Neill* in the allegedly obvious manner set forth in the Office Action. Specifically, as discussed above, *Watling* would not function as intended if it were modified in the manner set forth in the Office Action and it would require a large number of modifications which would not be obvious to one of ordinary skill in the art. Accordingly, Applicant respectfully requests that the

that the obviousness rejection of claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78 be withdrawn.

2. Claims 56, 60, 64, 67 and 68

Paragraphs 3-5 of the Office Action reject claims 56, 60, 64, 67 and 68 under 35 U.S.C. §103(a) as being unpatentable over the allegedly obvious combination of *Watling* and *O'Neill* in view of various other references. Specifically, claim 56 is rejected in view of U.S. Patent No. 6,589,479 to Dufresne et al. ("*Dufresne*"); claim 60 is rejected in view of UK Patent Application No. GB 2 360 454 A to Martin ("*Martin*"); and claims 64, 67 and 68 under 35 USC § 103(a) are rejected in view of U.S. Patent No. 5,173,258 to Childers ("*Childers*"). *Dufresne* is merely cited for allegedly disclosing using biological indicators to determine when the predetermined concentration of hydrogen peroxide/water vapor in the atmosphere has been reached. *Martin* is merely cited for allegedly disclosing using a recited percentage of hydrogen peroxide solution. *Childers* is merely cited for allegedly disclosing using a heating/ventilation air conditioning system to remove the hydrogen peroxide and to dehumidify the atmosphere within the enclosure.

Applicant submits that inasmuch as the rejection of claims 56, 60, 64, 67, and 68 relies on the purportedly obvious combination of *Watling* and *O'Neill* advanced by the Office Action in connection with the rejection of claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78, the rejection of claims 56, 60, 64, 67, and 68 lacks an adequate basis for at least the same reasons as discussed above with regard to claims 51-55, 57-59, 63, 65, 66, 69-72 and 74-78. As such, Applicant respectfully requests that the obviousness rejections of claims 56, 60, 64, 67, and 68 be withdrawn.

No other objections or rejections are set forth in the Office Action.

D. New Claims

Applicant submits that new claims 79 and 80 are distinguished over the cited art. For example, claims 79 and 80 recite that "the hydrogen peroxide/water vapour uniformly condenses on all of the surfaces within the enclosed space." Applicant submits that none of the cited art, taken together or separately, disclose these limitations in conjunction with the other limitations of claims 51 and 70, from which claims 79 and 80 respectively depend.

Furthermore, claims 79 and 80 respectively depend from claim 51 and 70 and thus incorporate the limitations thereof. As such, applicant submits that claims 79 and 80 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 51 and 70.

E. Conclusion

Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited art. Most notably, applicant submits that many if not all of the dependent claims are independently distinguishable over the cited art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited art.

In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 51-60, 63-72 and 74-78 as amended and presented herein.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to Deposit Account No. 23-3178: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any

addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefor and charge any additional fees that may be required to Deposit Account No. 23-3178.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this 4th day of March 2009.

Respectfully submitted,

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